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Biolase Technology, Inc.
Special 510(k)
EPICTM 10

Special 510(k) Summary for *EPIC*TM 10 by Biolase Technology, Inc. (As required by 21CFR 807.92)

SEP 2 8 2012

1. GENERAL INFORMATION

Date Prepared:

April 20, 2012

Company:

Biolase Technology, Inc.

4 Cromwell

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Submitter:

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VP, Regulatory, Quality and Clinical

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2. NAMES / REGULATIONS

Trade/Device Name:

EPICTM 10

Common Name:

Diode Laser

Regulation Number:

21CFR 878.4810, and 21CFR 890.5500

Classification name:

Laser surgical instrument for use in general and plastic

surgery and in dermatology; and infrared lamp

Regulatory Class:

Π

Product Code:

GEX, ILY

3. PREDICATE DEVICES

- ezlaseTM by Biolase Technology, Inc. K083069, K083595, K061898, and K082938
- *iLase*TM by Biolase Technology, Inc. K093852

Biolase Technology, Inc.

Special 510(k)

EPICTM 10

4. DEVICE DESCRIPTION

The *EPICTM* 10 system uses an Indium Gallium Arsenide Phosphorous (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a hand piece that emits the energy to the target site. A visible light is emitted at the same time to visually identify the treatment location. The *EPICTM* 10 Laser System is comprised of a Base Console, a detachable delivery system, tips, and a wireless footswitch. Various types of the single use tips are included for different applications and the device is activated by means of a wireless footswitch. The *EPICTM* 10 Laser is a surgical and therapeutic device designed for a wide variety of oral soft tissue procedures and dental whitening, as well as for use in providing temporary relief of minor pain.

5. INDICATIONS FOR USE

The indications are identical to that of the previously cleared predicate systems.

1. Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

Biolase Technology, Inc. Special 510(k) **EPICTM 10**

2. Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

3. Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

4. Pain Relief

• Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

6. DEVICE TECHNOLOGICAL CHARACTERISTICS

The device *EPICTM* 10 system has the same fundamental technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. A summary of the technological characteristics of this device in comparison to those of the company's owned predicate devices is included in the body of the special 510(k) submission.

7. PERFORMANCE ASSESSMENT

Non-clinical performance data is not presented. An Evaluation Report including the references, literature and publications is included in the 510(k) submission for the demonstration of safety and effectiveness of this device and to support substantial equivalence to the company's owned legally marketed devices.

The clinical test for the therapeutic heating device indications (Pain Therapy) listed in Item 4 of the IFU have been conducted with human subjects and the performance data demonstrated that the device can perform the pain therapy as described in the indication for use safely and effectively.

Biolase Technology, Inc. Special 510(k) EPICTM 10

8. CONTRAINDICATIONS

The contraindications are identical to that of the previously cleared ezlaseTM and $iLase^{TM}$ system by Biolase Technology, Inc.

All clinical procedures performed with *EPICTM* 10 must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, malignancies, bleeding disorders, sleep apnea, immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

9. SUBSTANTIAL EQUIVALENCE

The purpose of this Special 510(k) is to consolidate the current $ezlase^{TM}$ systems and the $iLase^{TM}$ system (K083069, K083595, K061898, K082938, and K 093852). It is a combination of indications for use and $EPIC^{TM}$ 10 system relies upon the company's owned legally marketed devices and no new indications for use are added. The design changes do not affect or potentially alter the fundamental scientific technology of the device. Based on the information presented in this Special 510(k) the combined system $EPIC^{TM}$ 10 is substantially equivalent to the sum of the legally marketed devices: $ezlase^{TM}$ and $iLase^{TM}$ systems.

The predicate device comparison table of the technological characteristics of the new device in comparison to those of the predicate device and the comparison table of the indications for use for each predicate and the subject device are shown in Appendix 1.

10. CONCLUSION

No new indications are added in this Special 510(k) and the device modifications do not potentially alter the fundamental scientific technology of the device. Substantial Equivalence for the $EPIC^{TM}$ 10 system has also been determined through comparison to the company's previous cleared devices. This Special 510(k) submission demonstrates that the $EPIC^{TM}$ 10 system is as safe, as effective, and performs as well as the predicate devices.

Device /	E 656575	eziase Tu	# SES	WOS mare 20W	H. 250 TE	EPIC™ 10	
Manufacturer	Biolase Technology, frc.	Biolase Technology, Inc.	Biolase Technology, Inc.	Biolose Technology, Inc.	Biolase Technology, Inc.	Biolase Technology, fnc.	
i	061698 Jenuary 26, 2007	K082938 December 22, 2008	K083595 April 14, 2009	K083069 November 23, 2008	K093852 March 12, 2010	Pending	
Laser	W(4)	N(4)	N(4)	N(4)	N(4)	W(4)	~
	Medical grade plastica, steel stainless steel, atuminum, brass, and electronic parts and components	Medical grade plastics, stock, stainless steek, aluminum, brass, and efectronic parts and components	Medical grade plastica, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastica, steel, staintess steel, aluminum, brass, and electronic parts and components	Medical grade plastica, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	~
Dimensions	3.5h x 7.0h x 2.5h (8.5cm x 18cm x 6cm)	3.5th x 7.0th x 2.5th (8.5cm x 18cm x 6cm)	3.5tn x 7.0tn x 2.5tn (8.5cm x 18cm x 6cm)	3.5hr x 7.0hr x 2.5hr (8.5cm x 18cm x 6cm)	4.7in x 4.0in x 2.8in (11.9cm x 10.2cm x 7.1cm)	5.7in x 4.4in x 6.5in (14.5cm x 11.2cm x16.5cm)	٠,
	2 lbs (1.0kg)	2 lbs (1.0kg)	2 lbs (1.0kg)	2 lbs (1.0kg)	1.89 lbs (0.85kg)	2.5 lbs (1.1kg)	.,
Operating Voltage	100 - 240 ~ at 2A	100 - 240 - at 2A	100 - 240 ~ at 2A	100 - 240 ~ #1 2A	90 - 230 VAC	100 - 230 ~ at 2A	•
Current Frequency	47 - 83 HZ	ZH 09~02	ZH 09 · 05	ZH 09 · 09	50 · 60 HZ	2H 09 - 09	v
sser Medium	GaALAs, InGaAsP	hGeAsP	GaAlds, InGaAsP	InGaAsP	InGaAsP	InGaAsP	-
Wavelength	815 ± 15nm, 935 ± 15nm	940 ± 15nm	810 ± 15nm, 940 ± 15nm	940 ± 15rm	940 ± 15nm	940 ± 10nm	2
Max Output	7 watts	12 watts	10 watts	10 watts	3.0 watts	10 watts	· -
Power Modes	Continuous, Putse Modulation	Continuous, Pulse Modulation	Continuous, Putse Modulation	Continuous, Pulse Modulation	Continuous, Pulse Modulation	Continuous, Putse Modulation	٠,
Pulse Repetition Rata	Upto 10KHz	Up to 10194z	Up to 10KHz	Up to 1010tz	Up to 10KRz	Up to 20194z	~
Putse Durattion	0.1 ms - 9.9 sec	0.05 ms - 10 sec	0.05 ms - 10 sec	0.06 ms - 10 sec	0.1 ms / 1 ms	0.01ms · 10 sec	~
Putse interval	0.1 ms - 9.9 sec	0.05 ms - 10 sec	0.05 ma - 10 sec	0.06 тэ - 10 зес	0.2 ms / 1 ms	0.01ms · 10 sec	•
Aining Beam	Laser Diode, max 1mW, 630-670mm, class 3B	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 38	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 38	Laser Diode, max 1mW, 635 ± 10nm, class 3B	. >
ğ	Approved Indication as per MIG1898	Indications for Approved Indication as Approved Indication as Use per K061638 per K062938	Approved indication as per K083595	Approved Indication as per K083069	Approved traication as per K0938/2 with Tissue refraction for impression	Same as those indications deared for ID61898, KD82938, KD83998, KD83998, KD83985, KD83862	-

Predicate	ezlase™	ezlase™	ezlase™	eziase™ 10W	iLase""	EPIC™ 10
510(k) No.	K061898	K082938	K083595	K083069	K093852	K121286
Indications for Use	1.Dental Soft Tissue Indications			1.Dental Soft Tissue Indications	1.Dental Soft Tissue Indications	1.Dental Soft Tissue Indications
	Incision, excision, vaporization,			Incision, excision, vaporization,	Incision, excision, vaporization,	Incision, excision, vaporization,
	coagulation of oral soft tissues			coagulation of oral soft tissues	coagulation of oral soft tissues	coagulation of oral soft tissues
·	including marginal and inter-dental			including marginal and inter-dental	including marginal and inter-dental	including marginal and inter-dental
	gingival and epithelial lining of free gingiva and		-	gingival and epithelial lining of free gingiva and	gingival and epithelial lining of free gingiva and	gingival and epithelial lining of free gingiva and
	the following specific indications:		÷	the following specific indications:	the following specific indications:	the following specific indications:
	• Excisional and incisional biopsies			• Excisional and incisional biopsies	• Excisional and incisional biopsies	 Excisional and incisional biopsies
	• Exposure of unerupted teeth			• Exposure of unerupted teeth	 Exposure of unerupted teeth 	 Exposure of unerupted teeth
	Fibroma removal Frenectomy			Fibroma removal Frenertomy	Fibroma removal Frenerfomy	• Fibroma removal

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Frenotomy		 Frenotomy 	• Frenotomy	Frenotomy
Gingival troughing for crown impressions		 Gingival troughing for crown impressions 	 Gingival troughing for crown impressions 	Gingival troughing for crown impressions
Gingivectomy		 Gingivectomy 	 Gingivectomy 	Gingivectomy
Gingivoplasty		 Gingivoplasty 	 Gingivoplasty 	Gingivoplasty
 Gingival incision and excision	·	 Gingival incision and excision 	 Gingival incision and excision 	 Gingival incision and excision
Hemostasis and coagulation		 Hemostasis and coagulation 	 Hemostasis and coagulation 	 Hemostasis and coagulation
Implant recovery		• Implant recovery	Implant recovery	Implant recovery
Incision and drainage of abscess		 Incision and drainage of abscess 	 Incision and drainage of abscess 	 Incision and drainage of abscess
Leukoplakia		• Leukoplakia	• Leukoplakia	• Leukoplakia
Operculectomy		Operculectomy	Operculectomy	Operculectomy
Oral papillectomies		Oral papillectomies	Oral papillectomies	Oral papillectomies
Pulpotomy		 Pulpotomy 	Pulpotomy	Pulpotomy
•Pulpotomy as an adjunct to root		Pulpotomy as an adjunct to root	•Pulpotomy as an adjunct to root	 Pulpotomy as an adjunct to root

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Bingival hypertrophy gingival hypertrophy gingival hypertrophy Soft tissue crown enginerable for the oral mucosa. Vestibuloplasty vestibuloplasty vestibuloplasty vestibuloplasty endomial periodomial periodomi		canal therapy			canal therapy	canal therapy	canal therapy
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Soft tissue crown lengthening Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. Vestibuloplasty Periodontal Procedures Laser soft tissue curettage Laser removal of diseased, infected, inflamed and necrosed soft		hypertrophy			hypertrophy	hypertrophy	hypertrophy
lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty • Laser Periodontal Procedures • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft		Soft tissue crown		,	• Soft tissue crown	• Soft tissue	• Soft tissue crown
• Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty • Laser Periodontal Procedures • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft		lengthening			lengthening	crown lengthening	lengthening
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inflamed and necrosed soft	,	Laser removal of			 Laser removal of 	diseased, infected,	diseased, infected,
inflamed and necrosed soft		diseased, infected,			diseased, infected,	inflamed and	inflamed and
necrosed soft		inflamed and			inflamed and	necrosed soft	necrosed soft
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tissue within the periodontal		tissue within the			tissue within the	periodontal	

	periodontal			periodontal	pocket	periodontal pocket
	pocket			pocket		
	•				Sulcular	Sulcular
	Sulcular			• Sulcular	debridement	debridement
. *	debridement			debridement	(removal of	(removal of
	(removal of			(removal of	diseased, infected,	diseased, infected,
	diseased, infected,			diseased, infected,	inflamed and	inflamed and
	inflamed and			inflamed and	necrosed soft	necrosed soft
	necrosed soft			necrosed soft	tissue in the	tissue in the
	tissue in the			tissue in the	periodontal	periodontal pocket
	periodontal			periodontal	pocket to improve	to improve clinical
	pocket to improve			pocket to improve	clinical indices	indices including
	clinical indices	,		clinical indices	including gingival	gingival index,
	including gingival			including gingival	index, gingival	gingival bleeding
	index, gingival			index, gingival	bleeding index,	index, probe
	bleeding index,			bleeding index,	probe depth,	depth, attachment
	probe depth,			probe depth,	attachment loss	loss and tooth
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	and tooth	e Light activation		and tooth	mobility.)	
	mobility.)	for bleaching		mobility.)		3.Whitening
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		whitening		,		for bleaching
		•				materials for teeth
		Laser-assisted	·			whitening
		whitening/bleaching				
		of teeth			,	 Laser-assisted
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			4. Pain Therapy			g of teeth
·			Topical heating			4.Pain Therapy
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		elevating tissue			 Topical heating
		temperature for a			for the purpose of
		temporary relief			elevating tissue
		of minor muscle			temperature for a
		and joint pain and			temporary relief of
		stiffness, minor			minor muscle and
		arthritis pain, or			joint pain and
	,	muscle spasm,			stiffness, minor
		minor sprains and			arthritis pain, or
		strains, and minor			muscle spasm,
		muscular back			minor sprains and
		pain; the	-		strains, and minor
	-	temporary			muscular back
		increase in local			pain; the
		blood circulation;			temporary increase
		the temporary			in local blood
		relaxation of			circulation; the
		muscle			temporary
					relaxation of
				,	muscle.
				•	
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Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Biolase Technologoy, Incorporated % Mr. Robert Y. Yang Global Regulatory Affairs Manager 4 Cromwell Irvine, California 92618

SEP 28 MR

Re: K121286

Trade/Device Name: EPIC[™] 10

Regulation Number: 21 CFR 878.4810, 890.5500

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in

dermatology, Infrared lamp

Regulatory Class: II Product Code: GEX, ILY Dated: September 17, 2012 Received: September 20, 2012

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Director

Division of Surgical, Orthopedic and Restorative Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

1 The divid

Biolase Technology, Inc. Special 510(k) EPICTM 10

Indications for Use

510(k) Number (if known): K121286

EPICTM 10 Device (Trade) Name:

Indications for Use:

1. Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

2. Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

3. Whitening

Light activation for bleaching materials for teeth whitenitigivision Sign-Off)

Laser-assisted whitening/bleaching of teeth

Division of Surgical, Orthopedic,

Neil RP Igden for mxn

and Restorative Devices

Biolase Technology, Inc. Special 510(k) EPICTM 10

4. Pain Therapy

Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

Prescription Use _	X
(Part 21 CFR 801	Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF **NEEDED**)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Surgical, Orthopedic,

and Restorative Devices

510(k) Number_K12128(